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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,916	11/21/2003	Paul Edward Kearney	50111/081002	7002
21559	7590	10/06/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			LIN, JERRY	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/719,916

Applicant(s)

KEARNEY ET AL.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-12, 21-24, 33-36, 45-48 and 57-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 13-20, 25-32, 37-44 and 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12, 21-24, 33-36, 45-48 and 57-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6 pages  
(2/10/06,10/5/05,6/23/04,6/21/04).

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group 1, Claims 9, 10, 21, 22, 33, 34, 45, 46, 57, and 58 and amended claims 11, 12, 23, 24, 35, 36, 47, 48, 59, and 60 in the reply filed on July 24, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

### ***Status of the Claims***

Claims 9-12, 21-24, 33-36, 45-48, and 57-60 are under examination.

Claims 1-8, 13-20, 25-32, 37-44, and 49-58 are withdrawn as being drawn to an unelected group.

### ***Information Disclosure Statement***

2. The International Search Report and the Written Opinion listed on the IDS filed February 10, 2006 has not been considered, because neither document is a publication. In addition the IDS filed June 21, 2003, June 23, 2003, and October 5, 2005, have been lined through, since the references are also listed on the IDS filed February 10, 2006.

### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 9-12, 21-24, 33-36, 45-48, and 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 9, 21, 33, 45, and 57 recite the limitation "the functions" in the first line of these claims. There is insufficient antecedent basis for this limitation in the claim. It is unclear to what function do the instant claims refer. There is not mention of any sort of function previously in the claim. It is also unclear what element's function is being determined. For example, the function could refer to the function of the peptides. Alternatively, the function could refer to the peptide maps.

6. The instant claims recite a "Peptide Map Alignment Module." It is unclear what this term means. A search of the prior art has not revealed any well-accepted definition, nor does the instant specification define the term. One interpretation of the term would be that it refers to a database of peptide maps. Another interpretation is that the term refers to some sort of algorithm that aligns the peptide maps. The later interpretation will be used for this office action.

7. The instant claims also recite a "column offset." It is unclear what this term means. A search of the prior art has not revealed any well-accepted definition, nor does the instant specification define the term. One interpretation is that the column offset refers to the particular physical or configuration of a column. Another interpretation is that the column offset refers to the time in which it takes to load a column.

8. Claim 9, 21, 33, 45, and 57 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap

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between the steps. See MPEP § 2172.01. The omitted steps are: the steps that incorporate the data from steps a), b) and c) to arrive at a function to align Peptide Maps. The method as claimed is drawn includes performing the peptide map alignment, determining a column offset, and determining a retention time transformation function. However one these three types of data are produced, the instant claims do not do anything further with the data. Thus, the instant claims do not arrive the function to align Peptide Maps. Furthermore, it is unclear what role do the claimed steps play in the method. Finally, it appears that the peptide maps are already aligned in step a). It is unclear why steps b) and c) are necessary.

9. Claims 12, 24, 36, 48, and 60 recite the limitation "the precursor" in line 3 of these claims. There is insufficient antecedent basis for this limitation in the claim. It is unclear if "the precursor" refers to the matched precursor or some other precursor that was not mentioned in the instant claims. Furthermore it is unclear that a peptide map would necessarily have a precursor.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 11, 23, 35, 47, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method wherein an alignment for a pair of peptide maps are produced and determining the differential intensities of biomolecules between the aligned maps which determines differentially and uniquely expressed biomolecules from the pair of injections.

The common understanding of the term "differential intensities" when used in the context of peptide maps is when a certain intensity is greater in one map than the other. However, the intensity refers to the same biomolecule in both maps. Thus it is unclear how a biomolecule can be uniquely expressed from differential intensities if the intensity is found in both maps and the intensity refers to the same biomolecule. Since the intensity refer to the same biomolecule, the claims contain subject matter that one of skill in the art would not be able to make or use the invention.

***Claim Rejections - 35 USC § 101***

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 9, 21, 33, and 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regards to claims 9, 21, 33, and 45, the instant claims are drawn to a mathematical algorithm. A mathematical algorithm is non-statutory unless the claims

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include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or an useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The method as claimed is drawn includes performing the peptide map alignment, determining a column offset, and determining a



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retention time transformation function. However one these three types of data are produced, the instant claims do not do anything further with the data. Thus, the instant claims do not arrive the function to align Peptide Maps. Thus the instant claims do not include any tangible result.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 9-11, 21-23, 33-35, 45-47, and 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorenstein (US 5,969,228).

The instant claims are drawn to a method of aligning peptide maps, determining the column offset and determining the retention time transformation function.

Regarding claims 9, 10, 21, 22, 33, 34, 45, 46, 57, and 58 Gorenstein teaches a method of creating peptide maps (column 4, lines 42-65); aligning the peptide maps with a peptide map alignment module (column 5, lines 45-65); determining the column offset between the pair of injections (column 7, line 10-33); determining the retention time transformation (column 12, line 25- column 14, line 2; column 6, Table 1).

Gorenstein et al. also teach implementing their method of computers, computer

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programs, computer systems, as well as displaying the information (column 2, lines 39-45; column 5, lines 19-34)

Regarding claims 11, 23, 33, 35, 47, and 59, Gorenstein teaches wherein the differences between the maps are determined (which would identify differentially expressed biomolecules) (column 5, lines 45-65).

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

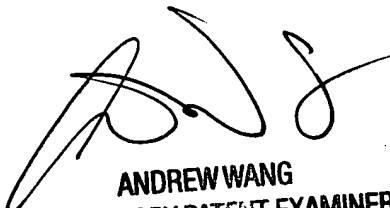
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